

Vaccinia Vaccine.

Areas that will be covered in this discussion:

- History of smallpox
- Transmission and manifestations of smallpox
- Current smallpox threat
- Vaccinia (smallpox vaccine) side effects
- Who **should** and **should not** receive the vaccine
- CDC recommendations for care of the injection site
- Questions for risk managers.

SMALLPOX HISTORY

- Smallpox is a highly contagious and sometimes fatal disease with no specific treatment.
- There are two clinical forms of smallpox.
- Variola major is the severe and most common form of smallpox, with a more extensive rash and higher fever. There are four types of Variola major smallpox:
 - **ordinary** (90% or more of cases);
 - **modified** (mild and occurring in previously vaccinated persons)
 - **flat and hemorrhagic** rare but with high mortality
- Historically, overall fatality rate of about 30%;
- Variola minor is a less common presentation of smallpox, and a much less severe disease, with death rates historically of 1% or less.

SMALLPOX HISTORY

- Blankets that had been infected with smallpox were given to the Indians by British soldiers during the French and Indian war in North America.
- Smallpox (*Variola major*) was declared eradicated by the World Health Organization (WHO) in 1979 the last case was reported in the US in 1949 and world wide, last in Somalia 1978.

TRANSMISSION

- **Generally and historically, direct and fairly prolonged face-to-face contact was required to spread smallpox from one person to another.**
- **Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing.**
- **Rarely, smallpox has been spread by virus carried in the air in enclosed settings such as buildings, buses, and trains. Humans are the only natural hosts of Variola. Smallpox is not known to be transmitted by insects or animals.**

TRANSMISSION

- Bio-terror attack using weaponized Smallpox could occur by inhalation of the airborne virus, especially in a Variola susceptible (unvaccinated) population.
- A person with smallpox is sometimes contagious with onset of fever (prodrome phase), but the person becomes **most contagious with the onset of rash**. At this stage the infected person is usually very sick and not able to move around in the community. The infected person is **contagious until the last smallpox scab falls off**.

CLINICAL MANIFESTATIONS

- 7-17 days after respiratory exposure.
- Febrile prodrome (2-3 days) with headache, back ache and vomiting, 15% of patients develop delirium.
- In 48-72 hours a rash appears on the face, upper extremities and oral mucosa.
- The palms and soles of the feet are commonly involved.
- The rash spreads centrally to the legs and the trunk during the second week.
- Lesions are synchronous and start as macules progressing to papules and then to pustules.
- Scabbing develops 7-14 days from the onset of the rash leaving behind hypopigmented depressed scars.
- Mortality in the unvaccinated is 30%.

TREATMENT

- **Treatment is supportive.**
- **No existing antiviral drugs have a proven clinical efficacy.**
- **Vaccination of exposed persons within 3-5 days has been shown to be effective in decreasing or preventing the development of smallpox.**

WHAT IS THE CURRENT THREAT

- Twenty tons of liquid Smallpox has been kept on hand at Soviet military bases.
- Bio-warheads on soviet ICBM missiles were test launched in the Pacific Ocean from 1989-1991
- Warheads unusually heavy and spinning wildly: thought to have had active refrigeration system to keep temperature near or below boiling temperature of water during re-entry.
- VECTOR pursued active weaponized smallpox research into the 1990's
- CIA has serious concerns about clandestine smallpox stocks: (Russia, China, India, Pakistan, Israel, Korea, Cuba, Serbia; links to Al Queda, Aum Shinriko.)
- Iraq 1994-1998 UNSCOM inspections noted concerns with buildings that confirmed work with camel pox had been done on the site.

CURRENT STATUS OF US THE POPULATION IMMUNITY TO SMALLPOX

- Routine vaccination ceased in the United States in 1972
- Previously vaccinated individuals confer 3-5 years after 5 years level of protection is unknown.

WHAT ARE THE IMPLICATIONS OF A SMALLPOX RELEASE

- A single person anywhere in the world would be considered a global medical emergency.
- Crude mortality rate 30%
- Response to an outbreak would require immediate, mass vaccination (post-event) campaign.
- Vaccination within 3-5 days of exposure to Smallpox can prevent the disease or at least decrease the symptoms.

WHAT IS THE SMALLPOX VACCINE

- Dryvax(Wyeth-Ayerst) is made from the **NYCBOH** strain of live virus from the stock that was used 30 years ago.
- The vaccine is made from a virus called vaccinia which is a “pox” type virus related to smallpox, but milder. It was prepared from infected calf skins infected with vaccinia; material was scraped from the lesions, freeze dried and added to antibiotics.
- The Dryvax is mixed 1:1 with diluent. 1 vial contains enough vaccine to vaccinate 100 persons
- The 1:5 dilution has not been approved by the FDA but will be used if an outbreak of Smallpox occurs.
- The smallpox vaccine contains the “live” Vaccinia virus, not dead virus like many other vaccines, and it does not contain Smallpox virus

The Smallpox Vaccine

- U.S. vaccine (Dryvax): 15.5 million doses
 - 1.7 million doses licensed
 - 1 million of doses for military
- Aventis Pasteur: 75-90 million doses
 - reserve
- Acambis/Baxter: 286 million doses
 - will not be licensed until late 2003, early 2004

The Smallpox Vaccine

- Smallpox vaccination provides high-level of immunity.
- Previously vaccinated individuals likely will have a faster “take” and less chance of serious side effects.
- If a person is vaccinated again later, immunity lasts even longer. Historically, the vaccine has been effective in preventing smallpox infection in 95% of those vaccinated (Based on data from the 60’s).

Who should get the Vaccine

- On December 13, 2002 President Bush announced a plan protect the American people against the threat of smallpox attack by hostile groups or governments.

Who should get the Vaccine

- Under the plan, the Department of Health and Human Services (HHS) will work with state and local governments to form volunteer Smallpox Response Teams who can provide critical services to their fellow Americans in the event of a smallpox attack.

Who should get the Vaccine

- Military and Department of Defense personnel are now receiving the vaccine (as of 12/13/02)
- Persons involved in the administration of the vaccine.(Health department vaccination teams)
- Persons who may come in contact with a person who has Smallpox.
- Individuals who wish to receive the vaccine on a voluntary basis absent an outbreak of smallpox.
 - **THE DECISION TO RECIVE THE SMALLPOX VACCINE IS A PERSONAL ONE
THE GOAL OF THIS PRESENTATION IS TO GIVE THE MOST UP TO DATE
INFORMATION TO ASSIST INDIVIDUALS IN MAKING AN INFORMED
DECISION.**

Who should not get the Vaccine

- Individuals who have any of the following conditions, or live with someone who does, should not get the smallpox vaccine unless they have been exposed to the smallpox virus.

Who should not get the Vaccine

- Persons with eczema or atopic dermatitis and other acute, chronic or exfoliative skin conditions.
 - Persons who have been diagnosed with with previously mentioned skin conditions even if the the condition is not active are at high risk of developing eczema vaccinatum.
 - Eczema vaccinatum is a potentially severe and sometimes fatal complication

Reaction after Vaccination

- Eczema vaccinatum. Serious skin rashes caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis.

Who should not get the Vaccine

- Skin conditions such as burns, chickenpox, shingles, impetigo, herpes, severe acne, or psoriasis.
 - If the potential vaccinee or any of their household contacts have the afore mentioned skin conditions, they are at high risk for inadvertent autoinoculation of the affected skin with vaccinia virus and should not be vaccinated until the skin condition resolves.

Who should not get the Vaccine

- Weakened immune system. Cancer treatment, an organ transplant, HIV, or medications to treat autoimmune disorders and other illnesses that can weaken the immune system.
 - If a potential vaccinee or any of their household contacts have conditions previously mentioned they should not be vaccinated.
 - People with these conditions are at a higher risk of developing a serious adverse reaction resulting from unchecked replication of the vaccinia virus (progressive vaccinia).
- HIV testing should readily available to all persons considering smallpox vaccination. Confidential testing is recommended for those with any history of HIV risk factors. Persons with a positive test result should be told not to be present at the vaccination site.

Who should not get the Vaccine

● Pregnancy

- All vaccines that contain live viruses are contraindicated during pregnancy.
- Before vaccination people should be asked if they or anyone in their household is pregnant or plans to become pregnant over the 4 weeks following vaccination.
- Routine pregnancy testing for women of child bearing age is not recommended.

● Under the age of 12 months.

- Or if there is a child in the home who is less than 1 year old.

● Breast-feeding.

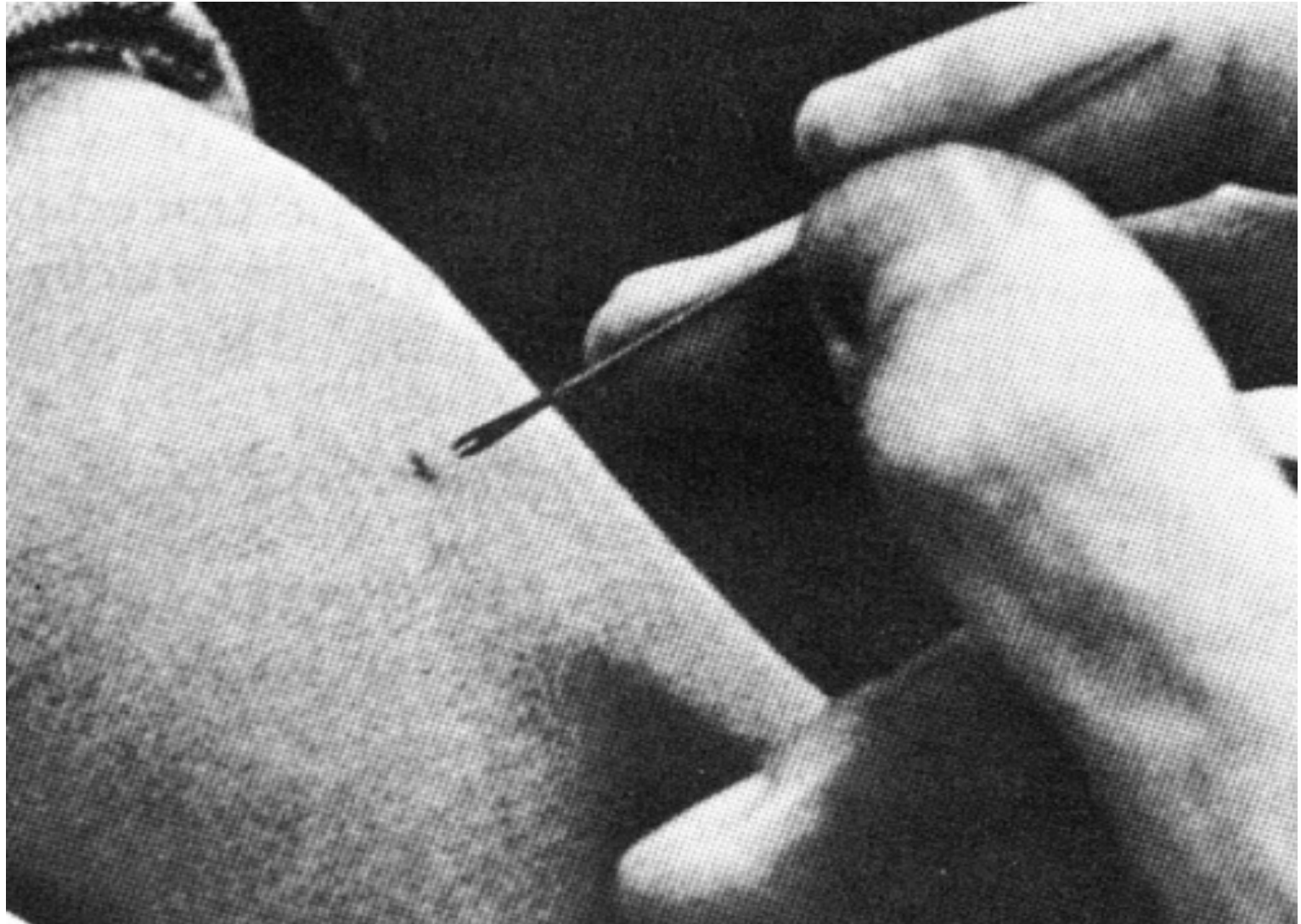
● Currently ill

- As with any vaccine, vaccination should be given in currently healthy individuals.

How the Vaccine is Given

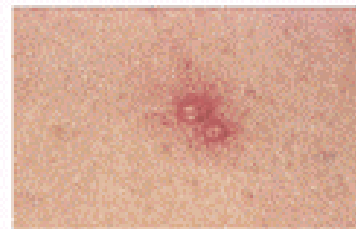
- The smallpox vaccine administered by scarification using a bifurcated (two pronged) needle that is dipped into the reconstituted vaccine solution.
- The vaccine is placed on a clean area of the skin. Alcohol will not be used to prep the skin.
- 15 rapid jabs to the skin in a circular fashion with the bifurcated needle to deliver the vaccine to the dermis.

Smallpox Vaccine Administration

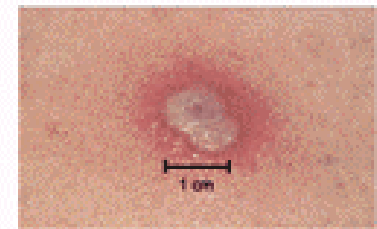


“TAKE REACTION”

- In the first week, the bump becomes a large blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and scar. People who have had the vaccine previously, have a faster progression of scabbing.



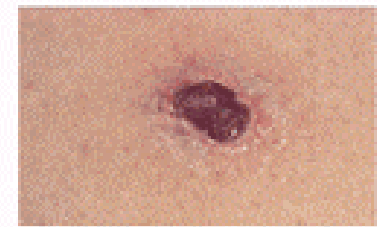
Day 4



Day 7



Day 14



Day 21

Post Vaccination Care

- After vaccination, it is important to follow care instructions for the site of the vaccine. Because the virus is live, it can spread to other parts of the body, or to other people.

- Autoinoculation occurs in about 1 per 1,900

CARE OF THE VACCINATION SITE

- The site should be covered with a dry dressing and held in place with a semi permeable bandage which should be changed every other day
- Bandage material carries live virus, proper hand washing and proper disposal of contaminated bandage material will prevent auto inoculation of unintended persons.
- Long sleeve shirts are recommended to avoid inadvertent scratching which would transfer the virus to other parts of the body or other persons.
- Proper washing and disposal procedures should be followed until the scab falls off. (14 - 21 days)

Expected Reaction after Vaccination

- Mild to moderate / self limiting side effects
 - The arm receiving the vaccination may be sore and red where the vaccine was given.
 - Mild rash, lasting 2-4 days.
 - Regional lymphatic swelling 2-4 weeks.
 - Generalized weakness “feel ill” in 20-30%, beginning on day 7-8. people may feel bad enough to miss work, school, or recreational activity or have trouble sleeping.
 - Fever >100 , 17%, >102 in 3% of vaccinated persons.

Moderate To Severe Reaction after Vaccination

● Moderate to severe side effects

- Generalized Vaccinia, vaccinia rash over the entire body (1 in 4,000)
- Eczema Vaccinatum severe rash, occurs independent of the current status of eczema condition. (1 in 26,000?).
- Post-vaccine Encephalitis allergic or autoimmune participant, 15 – 25% of patients will die. 25% will have permanent neurological symptoms. (1 in 83,000?)
- Vaccinia Necrosum/Progressive Vaccinia, non-healing site due to cellular-immunodeficiency, may be as many as (1 in 667,000 ?)
- Autoinoculation occurs in about 1 per 1,900
- Death
 - Primary vaccinees 1 per 2 million vaccinated
 - Re-vaccinees 1 per 4 million
 - Most complete nationwide smallpox safety data (1968) reported by Breman J and Henderson, DA in New England Journal of Medicine April 25 2002. Dan Hanfling, MD FACEP December 13, 2002

Reaction after Vaccination

- A vaccinia rash or outbreak of sore limited to one area. This is an accidental spreading to the vaccinia virus caused by touching the vaccination site and then touching another part of the body or person.



Reaction after Vaccination

- Vaccinia Necrosum/Progressive Vaccinia (non-healing site due to cellular-immunodeficiency) may be as many as 1 in 667,000 frequently leading to death.

Unanswered Questions for risk managers.

- Should vaccinated staff be “furloughed” to reduce the potential for auto inoculation?
 - Not recommended by Advisory Committee for Immunization Practices (ACIP)
- How should pre-screening be done and how far in advance of the receiving the vaccine?
- What are the liability issues for auto inoculation to a family member, employee or patient?
 - How will “take” monitoring be accomplished if an employee is off?

Initial Policy Issues

Smallpox Vaccination

- **How will the City manage “pre-vaccination” distribution of educational information / training to employees and their families?**
- **How will City conduct medical “pre-screening” for the presence of contraindications to the vaccine?**
- **Will the City provide any diagnostic testing for employees that may be unsure of their risk status? (ie. Pregnancy, HIV)**

Initial Policy Issues Smallpox Vaccination

- **How will an employee who is vaccinated as part of their reserve military service be treated ?**
- **How will vaccination reactions be treated under workman's compensation policies?**

Initial Policy Issues

Smallpox Vaccination

- How will an employee's family members be treated under the City's vaccination plan?**
- How will the City conduct the follow-up "take" examinations that are required to ensure that the vaccine was properly administered?**
- To what extent will the City provide employees and their families with medical supplies for required after care?**
- How will the City train employees and their families in caring for the injection site and the required safeguards associated with this "high risk" activity? (PPE, Biohazard waste)**

Initial Policy Issues

Smallpox Vaccination

- Non-emergency work requirements that may complicate vaccine site care and cleanliness must be modified / suspended. How will we manage this requirement?**
- Fire, EMS and Police activities place the vaccination site at risk for injury. What work modifications can be made to provide additional safeguards?**
- What temporary workplace requirements, policies, procedures must be enacted to safeguard others? (bed linens, blankets, laundering clothes, hand washing, etc.)**
- What waiver(s) will an employee who refuses the vaccine be required to execute in order to document that they rejected the employers offer for inoculation?**

Initial Policy Issues

Smallpox Vaccination

- **What will the City policy be for handling an employee who refused the voluntary vaccination, but is exposed to / or contracts smallpox?**
- **Will an “un-vaccinated” employee that is exposed to smallpox require “quarantine” until vaccinated post-exposure and medically released? What will the City’s policies be regarding this employee?**
- **How will the required medical and training records associated with the smallpox vaccination program be managed?**

Initial Policy Issues

Smallpox Vaccination

- Will the current health care providers cover any insurance claims with the inoculation process?
- Are there any preexisting medical conditions that would negate coverage for family members who may be auto inoculated?

For More information

- CDC Smallpox website

www.cdc.gov/smallpox

- International association of Firefighters

www.iaff.org

- National Immunization Program website

www.cdc.gov/nip

References

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